

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1 and 3 were amended by inserting “and a linker moiety, wherein the tag” and “(b) instructions; and (c) packaging means”. Claims 29 was amended by inserting “and a linker moiety” and “(d) instructions; and (e) packaging means”. Support can be found, *inter alia*, in paragraphs [0166] to [0172] and [0177], and in particular in paragraph [0169], as well as in Example 19 and the claims as filed. No new matter is entered.

Upon entry of this amendment, claims 1-14 and 20-27 and 29-36 are pending in the application. Claims 30-36 are withdrawn.

Claim rejections under 35 USC §102(b)

The Examiner rejected claims 1-5, 20-21 and 23-25 under 35 USC § 102(b) as anticipated by Houk et al. (*Analytical Chemistry*, (1980) 52:2283-2289). Applicants respectfully traverse this rejection.

The Examiner states that, while the instant claims recite a “kit” in the preamble, however the body of the claims read on reagent compositions. The Examiner goes on to apply Houk et al. simply because the reference discloses such reagents. Finally, the Examiner argues that Houk et al. discloses methods and reagents to measure positive ion mass and trace elements in ICP-MS procedures.

Applicants respectfully disagrees that Houk et al. teaches the reagent compositions of the claims. Rather, Houk et al. discloses the analysis of naturally occurring trace elements in solution, not isotopic tags that have been bound to biologically active materials. Accordingly, Houk et al. does not disclose any “tags” as required by the present claims. Houk et al. teaches isotopes, but these are not “tags” that bind to biologically active materials. The present claims recite “at least one tag, wherein the at least one tag comprises at least one isotope of a transition element and a linker moiety, wherein the tag is capable of directly tagging a biologically active material.” Tagging of the biologically active materials is described in paragraphs [0166] to [0172] and [0177] of the present invention. Houk et al. does not

disclose tagging a biologically active material with at least one isotope of a transition element and a linker element.

Further, Applicants amended independent claims 1, 3 and 29 by inserting “(b) instructions and (c) packaging means”. Support for “instructions” is found throughout the specification, for example in the claims as filed and in Example 19. Further, a skilled worker would understand that by definition, a kit includes packaging means. Houk et al. does not disclose a kit with isotopes for the analysis of tagged biologically active materials that includes instructions and packaging means. In addition, Houk et al. does not teach kits useful for tagging biologically active materials with isotopes. Houk et al. does not provide all the elements of the amended claims, therefore, as it does not disclose tagging a biologically active material with at least one isotope of a transition element and a linker element; nor does the reference teach or suggest, a kit as required by the present claims. Because Houk et al. cannot anticipate the present claims, Applicants request that the rejection be withdrawn.

Claim rejections under 35 USC §103

The Supreme Court has recently reaffirmed the *Graham* factors for the determination of obviousness. *See KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727,1739 (2007) 127 S. Ct. 1727 (2007) (holding that the proper inquiry for determining obviousness is whether the improvement is more than the predictable use of prior art elements according to their established functions). These four factual inquiries under *Graham* are: 1) determining the scope and contents of the prior art; 2) ascertaining the differences between the prior art and the claims in issue; 3) resolving the level of ordinary skill in the prior art; and 4) evaluating evidence of secondary consideration. *Graham v. John Deere*, 383 U.S. 17-18 (1966). In accordance with these factors, to establish a *prima facie* obviousness of the claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). Applicants assert that this burden has not been met.

II. Maggio

The Examiner rejected claims 6-9 as unpatentable over Houk et al. in view of Maggio (*Immunoenzyme Technique I*, (1980) CRC Press, pp. 186-187). Applicants respectfully traverse this rejection.

The Examiner states that Houk et al. differs from the claims 6-9 in not teaching reagent immobilization, but alleges Maggio discloses enzyme immunoassays wherein either the antigen or antibody is immobilized onto a solid phase.

As stated above, Houk et al. does not disclose a kit having an isotopic tag for directly tagging a biologically active material with an isotope of a transition element and a linker moiety, nor instructions and packaging means. Maggio does not remedy the deficiencies of Houk et al. Since the prior art references do not teach or suggest all of the claim limitations, they cannot render the present claims obvious. Therefore, Applicants request that the rejection be withdrawn.

III. Foster

The Examiner rejected claims 10-14 as being unpatentable over Houk et al. in view of Foster et al. (U.S. Pat. No. 4,444,879). Applicants respectfully traverse this rejection.

The Examiner states that Houk et al. differs from claims 10-14 in not disclosing reagents in kit configurations, including standards and buffers asserts that Foster et al. teaches these components.

As stated above, Houk et al. does not disclose a kit having an isotopic tag for directly tagging a biologically active material with an isotope of a transition element and a linker moiety, nor instructions and packaging means. Foster does not remedy the deficiencies of Houk et al. Since the references do not teach or suggest all of the claim recitations, no reasonable permutation of their teachings can render the present claims obvious. Therefore, Applicants request that the rejection be withdrawn.

IV. Neilson

The Examiner rejected claim 29 on the basis of obviousness with regard to Houk et al. in view of Neilson et al. (*Spectrochimica Acta Part B* (1998) 53:339-345), asserting that

Neilson et al. discloses laser ablation and gel electrophoresis. Applicants respectfully traverse this rejection.

Neilson et al. discloses a method to identify serum proteins that naturally bind metals (cobalt). There was no intention to label biological materials or analytes that do not normally bind metals, with transition elements. As stated above, Houk et al. does not disclose a kit having an isotopic tag for directly tagging a biologically active material with an isotope of a transition element and a linker moiety, nor instructions and packaging means. Neilson et al. does not remedy the deficiencies of Houk et al. Since the prior art references do not teach or suggest all of the claim limitations, they cannot render the present claims obvious. Therefore, Applicants request that the rejection be withdrawn.

V. Crooke:

The Examiner rejected claims 22 and 26-27 on the basis of obviousness with regard to Houk et al. in view of Crooke (WO 99/451450). The Examiner states that Crooke discloses the use of a “plurality” of tagged transition elements and biologically active materials. Applicants respectfully traverse this rejection.

The method of Crooke teaches ionization of the entire tagged biomolecule and the tag element itself, as required by the present claims. Applicant’s claimed invention is clearly distinguished from the method of Crooke because only the tag element is measured in the present method (not the tagged biomolecule). As stated above, Houk et al. does not disclose a kit having an isotopic tag for directly tagging a biologically active material with an isotope of a transition element and a linker moiety, nor instructions and packaging means. Crooke does not remedy the deficiencies of Houk et al. Since the prior art references do not teach or suggest all of the claim limitations, they cannot render the present claims obvious. Therefore, Applicants request that the rejection be withdrawn.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment accompany this response, the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then Applicants petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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